

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON**

UNITED STATES OF AMERICA

v.

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

Case No. 1:19-cr-00016

**UNITED STATES' RESPONSE IN OPPOSITION
TO INDIVIOR'S MOTION TO COMPEL**

The United States of America ("United States") opposes the Motion to Compel (Doc. 117) ("Mot.") and Memorandum in Support (Doc. 118) ("Mem.") of Defendants Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and Indivior plc (collectively, "Indivior") as follows.

INTRODUCTION

The United States has complied with *Brady v. Maryland*, 373 U.S. 83 (1963), and Federal Rule of Criminal Procedure 16, and will continue to do so. Indivior's Motion misapplies these laws to seek to entangle the United States in amorphous and impractical obligations. Contrary to Indivior's argument, neither *Brady* nor Rule 16 requires the United States to:

- search government offices that have not participated in the investigation;
- search for information not shown to be helpful to the defense; or
- itemize exculpatory and impeachment evidence for Indivior.

FACTS

The United States has supplied Indivior with all arguably exculpatory and impeaching information known to the investigative team, which is comprised of personnel from the:

- United States Attorney's Office for the Western District of Virginia ("USAO");

- Department of Justice, Civil Division, Consumer Protection Branch (“CPB”);
- Department of Justice, Civil Division, Commercial Litigation Branch (“CLB”);
- Food and Drug Administration, Office of Criminal Investigations (“FDA-OCI”);
- Dep’t. of Health and Human Services, Office of Inspector General (“HHS-OIG”);
- United States Postal Service, Office of Inspector General (“USPS-OIG”); and
- Virginia Attorney General’s Office, Medicaid Fraud Control Unit (“MFCU”).

This includes information the investigative team learned of and obtained, and has produced to Indivior on the ground it is arguably favorable to the defense, such as the:

- Food and Drug Administration, Center for Drug Evaluation and Research’s file regarding Suboxone Film, containing non-final, internal FDA comments on the safety claims Indivior submitted to the agency (“CDER File”);
- Substance Abuse and Mental Health Services Administration’s Treatment Improvement Protocol 40, reflecting unofficial opinions of a consensus panel that included Indivior’s vice president for clinical affairs (“TIP 40”);
- report of interview of Centers for Disease Control and Prevention, Medication Safety Program Director Dr. Daniel Budnitz, whom Indivior has cited in public statements regarding its safety claims about Suboxone Film (“Budnitz Interview”);
- document productions of, and reports of interviews and transcripts of testimony associated with, the Denver Health and Hospitals Authority (“DHHA”), Researched Abuse, Diversion, and Addiction-Related Surveillance System (“RADARS”), Rocky Mountain Poison and Drug Center (“RMPDC”), and Venebio Group, LLC (“Venebio”), whom Indivior has cited in public statements

regarding its safety claims about Suboxone Film (collectively, “Contract Researcher Files”); and

- public record of an Indiana state court bench trial – which happens to include exhibits created by the DEA – in which a physician who had served as a speaker for Indivior, and to whom Indivior’s “Here to Help” program had referred patients, was found not guilty of dealing in a Schedule III controlled substance (“Indiana Trial Record”).

Indivior is familiar with these items of information and has had the opportunity to explore them. In pre-indictment discussions from 2014 to 2019, Indivior and the United States exchanged views on many of them. In connection with the private civil antitrust case captioned *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, No. 2:13-md-2445 (E.D. Pa.), Indivior deposed the FDA on topics similar to those discussed in the CDER File, and obtained an affidavit from Dr. Budnitz regarding subjects similar to those covered in the Budnitz Interview. *See id.* (Doc. 513-26 at 3, n. 2) (Indivior brief on class certification).

Additionally, Indivior has had access to TIP 40 since it was issued in 2004, as Indivior’s vice president for clinical affairs was a member of the panel that issued it. *See* Excerpts from TIP 40 at 5 (attached hereto as Exhibit 1). Likewise, Indivior has had access to many of the Contract Researcher Files since they were created, as Indivior funded them. *See, e.g.,* Excerpt from Lavonas et al., *Abuse and Diversion of Buprenorphine Sublingual Tablets and Film*, *Journal of Substance Abuse Treatment* 47 (2014) at 2 (attached hereto as Exhibit 2) (“This research was funded by a grant from Reckitt-Benckiser Pharmaceuticals,” a/k/a Indivior).

In sum, Indivior has had a high degree of access to the core information arguably favorable to its defense for years.

LAW AND ARGUMENT

Indivior bypasses the case law defining the scope of *Brady* and Rule 16, and argues it has an “understanding and belief” that the following agencies possess “evidence material to its defense” and therefore the United States must search them:

- Department of Health and Human Services (“HHS”);
- Centers for Disease Control and Prevention (“CDC”);
- Centers for Medicare and Medicaid Services (“CMS”);
- National Institutes of Health (“NIH”);
- National Institute on Drug Abuse (“NIDA”);
- Substance Abuse and Mental Health Services Administration (“SAMHSA”);
- Food and Drug Administration (“FDA”);
- Drug Enforcement Agency (“DEA”); and
- National Academies of Sciences, Engineering, and Medicine (“National Academies”).

Mem. at 3-5. Indivior further contends its 14 attorneys, from some of the largest law firms in the country, “cannot be expected to undertake a massive effort and spend months wading through 800,000 documents” the United States provided to the company months ago in searchable electronic format with metadata, so the United States must “identify all exculpatory and impeachment information.” Mem. at 18-21.

A. The United States Need Not Search Offices that Have Not Participated in the Investigation for Information Not Known to the Investigative Team

As a preliminary matter, *Brady* requires the United States to produce evidence in its possession that is favorable to Indivior and material to guilt or punishment. *See* 373 U.S. at 87. This includes impeachment evidence. *See Giglio v. United States*, 405 U.S. 150, 154 (1972).

Evidence is in the United States' possession if it is known to those "acting on the government's behalf in the case," *see Kyles v. Whitley*, 514 U.S. 419, 437 (1995), sometimes called the "investigative team" or "prosecution team," *see, e.g., United States v. Robinson*, 627 F.3d 941, 951 (4th Cir. 2010). Rule 16(a)(1)(E)(i) requires the United States to produce upon request items in its possession that are material to preparing the defense.

Neither *Brady* nor Rule 16 obligates the United States to supply Indivior with evidence that is not known to the investigative team. The composition and limits of the investigative team depend on the facts. *See Robinson*, 627 F.3d at 952 ("[w]e draw no hard and fast lines here about the scope of *Brady* imputation"). However, courts have rejected the notion that the investigative team extends beyond the offices of the personnel conducting the investigation, to encompass entire federal agencies or departments. For example, in *United States v. Pearson*, No. 1:15-cr-193, 2016 WL 7647523, at *3 (E.D. Va. Aug. 11, 2016), the court held that an investigative team led by the United States Attorney's Office for the Eastern District of Virginia did not include the DEA, even though both are components of the Department of Justice, because no DEA personnel participated in the investigation. In *United States v. Brodnik*, 710 F.Supp.2d 526, 545 (S.D. W.Va. 2010), the court reasoned that although IRS personnel participated in the investigation, "there is no indication that the prosecution and the IRS personnel or offices who promulgated the materials requested by [the defendant] engaged in a joint investigation," and the "fact that IRS agents participated in this investigation does not mean that the entire IRS is properly considered part of the prosecution team." In *United States v. Milton*, No. 95-cr-74, 1996 WL 324401, at *4 (W.D. Va. May 30, 1996), the court ruled that the United States had a "duty to discover and reveal material, exculpatory evidence that is known to its agents and law enforcement officers working on its behalf in the case," but not "to gather

information from local law enforcement agencies from New York to the Carolinas” which were not working on the case. In *United States v. Pelullo*, 399 F.3d 197, 218 (2005), the Third Circuit concluded, “[defendant’s] arguments to the contrary notwithstanding, that other agents in the [Department of Labor] participated in this investigation does not mean that the entire DOL is properly considered part of the prosecution team.” In *United States v. Avellino*, 136 F.3d 249, 255 (1998), the Second Circuit observed that “the imposition of an unlimited duty on a prosecutor to inquire of other offices not working with the prosecutor’s office on the case in question would inappropriately require us to adopt a monolithic view of government that would condemn the prosecution of criminal cases to a state of paralysis.” (Quotations omitted.)

Indivior’s legal analysis relies on quoting from cases without examining their holdings. In *Kyles*, 514 U.S. at 438-41, personnel from the police department that investigated the case failed to disclose to the prosecutor, who in turn failed to disclose to the defense, eyewitness statements taken by the police at the murder scene; an informant’s statement to the police; and a list of cars parked at the murder scene, which did not include the defendant’s car. The decision does not speak to the issue Indivior has raised regarding the scope of the investigative team. Meanwhile, in *Horton v. United States*, 983 F. Supp. 650, 654 (E.D. Va. 1997), the court held that an investigative team led by the United States Attorney’s Office for the Eastern District of Virginia did not possess records of a state prison, finding, “the United States Attorney’s Office had no obligation under *Brady* to turn over a document that was part of [the defendant’s] file at Lorton [Correctional Complex], a nonfederal facility, but that was not in the possession of the prosecution or any of its investigative agents.” *Id.* at 655. The decision does not aid Indivior’s argument. Neither *United States v. Stever*, 603 F.3d 747 (9th Cir. 2010), nor *Carriger v. Stewart*, 132 F.3d 463 (9th Cir. 1997), analyzes whether *Brady* or Rule 16 requires the government to

search offices that have not participated in the investigation. In the lone case appearing to support Indivior's position, *United States v. W. R. Grace*, 401 F. Supp. 2d 1069, 1078 (D. Mont. 2005), the court explained it was not applying the "'prosecution team' concept" adopted in other circuits, thus its analysis is inapplicable here.

B. The United States Need Not Search for Evidence Not Shown to Be Helpful to the Defense

Neither *Brady* nor Rule 16 permits discovery based on relevancy. See *Weatherford v. Bursey*, 429 U.S. 545, 559 (1977) ("There is no general constitutional right to discovery in a criminal case, and *Brady* did not create one"); *United States v. Caro*, 597 F.3d 608, 619 (4th Cir. 2010) ("*Brady* requests cannot be used as discovery devices"); *United States v. White*, No. 15-cr-6193, 2016 WL 2989567, at *2-4 (D. Md. May 24, 2016) (under Rule 16, "[n]either a general description of the information sought nor conclusory allegations of materiality suffice; a defendant must present facts which would tend to show that the Government is in possession of information helpful to the defense"). They do not contemplate the exercise Indivior seems to envision, in which the United States would seek to identify custodians and repositories of potentially relevant documents within federal agencies, then collect and review the documents for responsiveness and production, as in a civil case. Rather, here, the United States has already given Indivior all evidence in its possession arguably favorable to the defense, and to compel the United States to produce more, Indivior must "present facts showing that the requested information will actually help prove [its] defense, not merely that it might help prove [its] defense." *White*, 2016 WL 2989567 at *4 (applying *Caro*, 597 F.3d at 621).

In *Caro*, 597 F.3d at 609-10, the defendant was tried for murder, convicted, and sentenced to death. On appeal, he challenged the district court's denial of his motions under *Brady* and Rule 16(a)(1)(E) for records of the Bureau of Prisons ("BOP") such as "[m]ovement

sheets from the central inmate file on every inmate who has killed another inmate.” *Id.* at 617, 619-22. The Fourth Circuit affirmed the district court’s denial of the motions, holding:

We have often noted that *Brady* requests cannot be used as discovery devices. . . . The district court denied [the defendant’s] motion under *Brady* because [the defendant] failed to establish that the information requested would be favorable to him. We agree. Because [the defendant] can only speculate as to what the requested information might reveal, he cannot satisfy *Brady*’s requirement of showing that the requested evidence would be favorable to [the] accused. . . . [While] the disclosure required by Rule 16 is much broader than that required by the due process standards of *Brady*, [f]or the defendant to show materiality under [Rule 16(a)(1)(E)(i)], [t]here must be some indication that the pretrial disclosure of the disputed evidence would have enabled the defendant significantly to alter the quantum of proof in his favor. . . . Caro presented no facts whatsoever indicating that the information would have actually helped prove his defense. . . . For this reason, the district court did not abuse its discretion by finding that the requested information was not material to preparing the defense.

Id. at 619-22 (citations and quotations omitted).

In a recent application of *Caro*, *United States v. Ducore*, 309 F.Supp.3d 436, 440 (E.D. Va. 2018), the defendant was indicted on one count of interference with flight crew members and flight attendants. The defendant made a *Brady* request for information regarding other passengers on the flight. The court reasoned the request “*might* produce statements that are exculpatory or statements that *might* impeach the government’s flight attendant witnesses.” *Id.* (emphasis in original). The court concluded the request “fail[ed] at the threshold, as the Fourth Circuit has held that where, as here, a defendant can only speculate as to what the requested information might reveal” she “cannot satisfy *Brady*’s requirement of showing the requested evidence would be favorable to the accused.” *Id.* (quoting *Caro*, 597 F.3d at 615). *See also United States v. Matish*, 193 F. Supp.3d 585, 598 (E.D. Va. 2016) (holding speculation insufficient under Rule 16(a)(1)(E)(i)).

Indivior's Memorandum does not appear to offer legal analysis regarding the materiality requirement. This omission is noteworthy because Indivior seeks broad categories of documents based on speculation as to what they *might* contain and how they *could* help the defense, which is inconsistent with *Caro*.

C. Indivior's Motion Seeks Information Not Known to the Investigative Team and Not Shown to Be Helpful to the Defense

There are two separate, independent bases to deny Indivior's Motion. First, the information Indivior seeks is not known to the investigative team. Second, Indivior has not shown the information would help its defense.

1. **SAMHSA.** Indivior argues the United States must search the SAMHSA, on the ground that the SAMHSA "is responsible for overseeing a physician's ability to prescribe buprenorphine-containing products [and] has issued guidance on the use of buprenorphine for the treatment of opioid addiction, and has advised – contrary to the allegations in the government's Indictment . . . that dosing at amounts up to 32 mg per day is recommended for certain patients." Mem. at 9-10. Indivior's argument should be rejected.

- Nobody from the SAMHSA has participated in the investigation, and the investigative team has no knowledge of additional information residing at the SAMHSA. The investigative team downloaded TIP 40 from the SAMHSA's public website, and supplied it to Indivior on the ground it is arguably favorable to the defense.
- Indivior has not shown that any particular information residing at the SAMHSA will help the defense. Indivior's speculation the United States would be "likely to find" exculpatory material "after a search," Mem. at 9-10, is precisely the type of request foreclosed by *Caro*. Additionally, Indivior's assertion that the SAMHSA

has “issued guidance” that “dosing at amounts up to 32 mg per day is recommended for certain patients,” Mem. at 9, is false and deleterious, reflecting disregard for accuracy of scientific information. For one thing, TIP 40 expressly states that it offers “the views of the consensus panel members [which] do not necessarily reflect the official position of CSAT, SAMHSA, or DHHS,” and has “[n]o official support.” *See* TIP 40 at 2 (Exhibit 1). For another, it is outdated, having been issued more than 15 years ago by a consensus panel that included Indivior’s vice president for clinical affairs, *see id.* at 5; states that nearly all patients will stabilize on doses of 16-24 mgs, with some possibly requiring up to 32 mgs (as opposed “recommending” 32 mgs), *see id.* at 6; and was superseded by Suboxone Film’s FDA-approved labeling, which states that dosages higher than 24 mgs “have not been demonstrated to provide any clinical advantage,” *see* Except from Suboxone Film Label at 3 (attached hereto as Exhibit 3). For these reasons, it is unlikely that documents retrieved in a search of the SAMHSA will help the defense.

2. **CDC.** Indivior argues the United States must search the CDC, on the ground that a CDC employee, Dr. Budnitz, published a seven-paragraph piece in the CDC’s Morbidity & Mortality Weekly Report concerning unit-dose packaging of buprenorphine drugs. Mem. at 10, n. 9. Indivior’s argument is illogical.

- Nobody from the CDC has participated in the investigation. The investigative team’s contact with the CDC involved interviewing Dr. Budnitz, after Indivior obtained an affidavit from him. The investigative team has supplied the interview

report to Indivior, on the ground it is arguably favorable to the defense. The investigative team has no knowledge of additional information residing at CDC.

- Indivior has not shown that any particular information residing at the CDC will help the defense. Moreover, Indivior's course of action in obtaining an affidavit from Dr. Budnitz by indicating it was for use in private civil antitrust litigation – without disclosing that the company was under investigation by the Department of Justice, which may have led Dr. Budnitz not to supply an affidavit – and then citing the affidavit in public “rebuttals” of the Indictment without consulting Dr. Budnitz, suggests additional information in the possession of the CDC may not be favorable to the defense. *See* Statement of Indivior on Grand Jury Indictment at 2, available at <http://www.indivior.com/wp-content/uploads/2019/04/INDV-Indictment-Press-Release-FINAL-.pdf> (last visited Sept. 13, 2019).

3. **CMS, NIH, NIDA, and National Academies.** Indivior argues the United States must search these offices because the entire HHS “actively participated as a member of the prosecution team,” and these offices have information regarding issues such as “the benefits of MAT.” Mem. at 10-12.

- Nobody from these offices participated in the investigation.
- Indivior reduces its own argument to absurdity. Unspecified information on the benefits of medication-assisted treatment potentially residing at the National Institutes of Health cannot seriously be characterized as *Brady* or Rule 16 material. The efficacy of medication-assisted treatment is not at issue.

4. **DEA.** Indivior argues the investigative team must search the DEA because the DEA registers, and may investigate, physicians who prescribe and pharmacies which dispense controlled substances, including Suboxone. Mem. at 12-14.

- The DEA has not participated in the investigation. The DEA has not interviewed witnesses, obtained documents, reviewed evidence, or attended meetings in this case. The investigative team has not ignored DEA activities, and it noted the DEA's involvement in the prosecution of a doctor in Indiana who Indivior had paid to give speeches, and to whom Indivior had referred patients, for dealing in a Schedule III controlled substance. The investigative team obtained the publicly available Indiana Trial Record, which includes exhibits created by the DEA such as videotapes, and produced it to Indivior on the ground it is arguably favorable to the defense, as well as other information it learned about the DEA's investigation of the Indiana case.
- Indivior has not shown that any particular DEA information would help its defense. Indivior reasons that the DEA may or may not have investigated the doctors referenced in the Indictment, and may or may not have taken action against them, which Indivior may seek to use to exculpate itself by shifting blame to the DEA. Mem. at 12-14. However, the allegations against Indivior concern Indivior's marketing and patient referrals to doctors Indivior (not the DEA) determined were, in the words of an Indivior manager, engaged in "very careless and clinically unwarranted prescribing behaviors," *see* Superseding Indictment (Doc. 115) at 27. Even assuming, *arguendo*, that the DEA had information indicating specific doctors were inappropriately prescribing Suboxone, the DEA's

knowledge would not be material to Indivior's knowledge. The Indictment does not allege Indivior had knowledge of DEA activities, and Indivior has not claimed it had any knowledge about the DEA investigating or not investigating doctors, or taking or failing to take enforcement actions. Accordingly, Indivior has not shown that information in possession of the DEA is helpful to the defense. Indivior's follow-on argument that it is entitled to DEA information regarding "pharmacies that filled the prescriptions alleged to have been improperly written" is similarly irrelevant. Indivior's next request is pure speculation, as the investigative team has no knowledge of, and Indivior has not identified, any "study and assessment" of "the diversion disparities between Suboxone film and Suboxone tablets" authored by the DEA. Indivior's request for "any documentation or other information reflecting instances in which Indivior itself reported information regarding registered physicians to the DEA" is illogical as Indivior would know of any such report.

5. **FDA.** Indivior argues the CDER File, which the United States extracted from the FDA's computer system and supplied to Indivior, is insufficient because Indivior "would expect to see in the government's production a wide range of internal and external communications, detailed analyses, and records reflecting inter-agency collaboration." Mem. at 16.

- Neither the CDER, nor other research offices within the FDA, took part in the investigation. When the investigative team learned that comments arguably favorable to the defense were contained in the CDER File, the team diligently obtained the file, and has produced it to Indivior. The investigative team is not

aware of additional information in the possession of the FDA that is arguably favorable to the defense.

- Indivior speculates that “there is reason to believe there are substantial additional material documents in the FDA’s files . . . which will include, but not be limited to, email communications and other correspondence” Mem. at 17. This resembles a civil discovery request. It does not show the FDA has evidence that will help the defense. Indivior’s claim that some within the FDA “agreed with many points raised by the company” in internal commentary ignores that Indivior had deceived them by concealing that it had marketed Suboxone Film as safer throughout the study period; that the commentary contained internal inconsistencies (as may be expected in deliberative communication); and that the FDA’s final, public response did not agree with Indivior and referred the company for investigation by the Federal Trade Commission.

D. The United States and Indivior Have Already Identified the Core Information Arguably Favorable to the Defense; the United States Need Not Itemize It

As noted above, the United States and Indivior have discussed information arguably favorable to the defense in meetings dating back to 2014. The United States has also produced documents to Indivior in searchable electronic format with metadata. Indivior has at its disposal 14 attorneys from three major law firms, as well as other attorneys and staff from those and other law firms, to perform a document review, and \$988 million in cash. *See* Indivior H1 2019 Results at 5, available at www.indivior.com/wp-content/uploads/2019/07/Indivior-2019-H1-Financial-Results-Presentation.pdf (last visited September 13, 2019).

These facts do not justify ordering the United States to review documents for Indivior. *See, e.g., United States v. Warshak*, 631 F.3d 266, 297 (6th Cir. 2010) (absent bad faith, “the

government is under no duty to direct a defendant to exculpatory evidence within a larger mass of disclosed evidence’’) (quoting *United States v. Skilling*, 554 F.3d 529 (5th Cir. 2009)); *Pelullo*, 399 F.3d at 212-13 (government not obligated to point defendant to exculpatory and impeachment information in warehouse of documents); *United States v. Ferguson*, 478 F.Supp. 2d 220, 241-42 (D. Conn. 2007) (government provided documents to defendant in searchable electronic format and was not required to itemize exculpatory matter).

The cases cited by Indivior are readily distinguishable. In *United States v. Salyer*, No. 10-0061, 2010 WL 3036444, at *7 (E.D. Cal. Aug. 2, 2010), the court ordered the government to identify exculpatory information for an “individual defendant, who [was] detained in jail pending trial, and who [was] represented by a relatively small defense team.” See *United States v. Lacey*, No. 18-cv-00422, 2018 WL 4963292, at *3 (D. Ariz. Oct. 15, 2018) (distinguishing *Salyer* and *United States v. Hsia*, 24 F. Supp. 2d 14 (D.D.C. 1998), and denying motion to compel the government to identify *Brady* material within 10.4 million documents produced in searchable electronic format to defendants with substantial resources). Similarly, in *United States v. Blankenship*, No. 5:14-cr-00244, 2015 WL 3687864, at *5 (S.D. W.Va. June 12, 2015), the court addressed concerns that the government’s production was not easily searchable in time for the trial. Such concerns do not apply here.

CONCLUSION

Indivior’s Motion to Compel (Doc. 117) should be denied.

Respectfully submitted,

DANIEL P. BUBAR
First Assistant United States Attorney
Attorney for the United States, Acting Under
Authority Conferred by 28 U.S.C. § 515

/s/ Albert P. Mayer, VSB No. 86024
Carol L. Wallack
Randy Ramseyer
Kristin L. Gray
Joseph S. Hall
Garth W. Huston
Janine M. Myatt
United States Attorney's Office
180 West Main Street
Abingdon, VA 24210
Tel: (276) 628-4161
Fax: (276) 628-7399
Email: albert.p.mayer@usdoj.gov

CERTIFICATE OF SERVICE

I certify that on September 13, 2019, I electronically filed the foregoing Response in Opposition to Indivior's Motion to Compel with the Clerk of Court via the CM/ECF system, which will send notification of the filing to all counsel of record in this matter.

/s/ Albert P. Mayer, VSB No. 86024